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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,722	10/19/2001	Seishi Kato	2001_1023A	8828
513	7590	06/23/2004	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/889,722

**Applicant(s)**

KATO ET AL.

**Examiner**

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1,4 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 1-9 are pending in the present application. Claims 1, 4, and 7 are withdrawn from consideration as being drawn to a non-elected invention. Claims 2, 3, 5, 6, 8 and 9 are currently under consideration.

#### ***Response to Amendment***

Claims 2, 3, 5, 6, 8 and 9 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons already of record.

Claims 2, 3, 5, 6, 8 and 9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### ***Response to Arguments***

Applicant's responses to the above rejections are noted. However, these arguments are not found persuasive for the reasons set forth below.

Applicant generally argues that the examiner has failed to establish by a preponderance of the evidence that neither a specific asserted nor well-established utility exists for the present invention. Applicant argues that specific utilities have been disclosed for the instant invention. These utilities include: the use of the polynucleotide of SEQ ID NO:2 as a probe for the diagnosis of various diseases, such as cancer, the use of the polynucleotide of SEQ ID NO:2 as a

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source for gene therapy, the use of the polynucleotide of SEQ ID NO:2 in expression vectors to produce the human nuclear protein of SEQ ID NO:1, the use of the human nuclear protein of SEQ ID NO:1 for the diagnosis and therapy of various diseases, including cancer, and the use of the human nuclear protein of SEQ ID NO:1 for the generation of antibodies with diagnostics and research application. Without addressing each of these asserted utilities individually, it is asserted that these utilities listed are not specific asserted utilities. MPEP 2107.01 states: "A 'specific utility' is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention." Without specific knowledge as to the function of the polynucleotide of SEQ ID NO:1 or the protein it encodes, each of these utilities is a general assertion and not a specifically asserted utility. Applicant makes a general statement of diagnostic and treatment utilities for the claimed sequence. However, the biological activity of that sequence is not established. Therefore, a specific utility for the claimed polynucleotide has not been asserted.

Applicant argues that a biological activity of the polynucleotide is established based on homology data which discloses a WW domain in the sequence and that the specification teaches that human nuclear receptors have various well-established functions. In support of their position that WW domains have well-established utilities Applicant has provided a PubMed search of WW domains. Applicant's assertions are noted. However, even these arguments provided support the conclusion that the present sequence does not have a well-established utility. In Applicant's specification, table 1, discloses a comparison of various sequence with homology to the WW domain of the present invention. First, as discussed in detail in the prior Office action, Applicant is reminded that homology does not necessarily correlate to function

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which is recognized in the art cited by the examiner. It is noted that Applicant has not addressed the merit of the art previously cited in the present response. Second, WW domains are found in protein with varied functions such that the mere presence of a WW domain does not correlate to biological activity, as Applicant asserts. The WW domain is related to proteins with many activities such as “transcription factors, splicing factors, intranuclear receptors, cell cycle regulators, tumor suppressors etc.” See Applicant’s remarks, page 7 and Specification, page 1. Moreover, in considering the compared sequences in table 1, Accession number P476937, which also has a WW domain, is disclosed by Chen et al. J. Biol. Chem. Vol. 272 no. 27 pp17070-7 1997. Chen et al. also recognize the diversity of proteins having WW domains: “the WW domain is shared by proteins of diverse functions including structural, regulatory, and signaling proteins in yeast, nematode and mammals.”

Moreover, the cDNAs encoding the proteins, which are disclosed by Chen et al. and referred to by Applicant as a reference for establishing WW domain homology, “represent novel proteins with **no known** function.” See Chen, abstract. Thus, it is impossible to extrapolate based on even the sequence comparison data from table 1 in the specification the biological activity of SEQ ID NO:1 and the protein it encodes. Applicant has therefore failed to establish whether this specific sequence with a WW domain has a well-established utility. If WW domains were associated with a specific protein and its activity, perhaps utility would have been established. Given the disclosure of the specification and the art, Applicant has at best established that WW domains have well-established utilities in mediating protein-protein interactions. This, however, does not satisfy the requirement that the invention, *i.e.* the

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polynucleotide of SEQ ID NO:2, have a well-established utility. Therefore, the rejection above is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



JAMES KETTER  
PRIMARY EXAMINER